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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,245	09/08/2003	Gary J. Mullen	GMMD-1-1002	8853
25315	7590	08/25/2005	EXAMINER	
BLACK LOWE & GRAHAM, PLLC 701 FIFTH AVENUE SUITE 4800 SEATTLE, WA 98104			MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/656,245

Applicant(s)

MULLEN, GARY J.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/15/03 & 3/31/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings were received on 1/26/04. These drawings are acceptable.

### ***Claim Objections***

1. Claims 7 and 8 are objected to because of the following informalities: Claims 7 and 8 should depend from claim 6 rather than claim 1, since "said pull handle" is disclosed in claim 6, not claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-5, 9-16, 18-20, 23-24, and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock (2003/0018309) in view of Shea (4,813,941). Breznock discloses applicant's basic inventive concept of an apparatus for treating pneumothorax and/or hemothorax, substantially as claimed with the exception of an

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adhesively coated tab configured to secure the hub of the device to the skin. Shea (4,813,941) shows this feature to be old in the medical art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity.

5. Regarding claim 1, Breznock discloses a trocar with stylet and point for puncturing the body (fig 3A) and stopper (fig 3B); he also discloses a tube with lumen to receive stylet with open-ended portion and at least one fluid opening (fig 3B); he also demonstrates a hub and one-way valve continuous with lumens of tube and hub (fig 5A).

6. In regards to claims 2 and 23, Breznock discloses the point on the stylet extending beyond the proximal portion of the tube when said stylet is inserted into catheter assembly (fig 3B) and brings stopper into engagement with the hub.

7. Regarding claims 3 and 24, Breznock shows the diameter of the stopper to be larger than the diameter of the lumen of one-way valve (fig 3B).

8. Regarding claim 4, Breznock shows a portion of the stopper is removably retainable in at least a portion of the hub (fig 3B).

9. Regarding claims 9 & 28, Breznock shows an annular recess on outside wall of hub (fig 3B).

10. Regarding claims 10, 11, 29, Breznock shows one-way valve secured to hub by retaining ring position over said one-way valve within recess by at least one band and the adhesive tab is attached to band for securing the device to the patient (0015-0017).

11. Regarding claims 12 and 31, Shea discloses at least one tab including a removable covering (column 4 lines 4-6).

12. Regarding claims 13 and 30, Breznock discloses a disk coupled to catheter assembly for securing trocar to patient (0016).

13. Regarding claims 14 and 32, Breznock discloses at least one of said stylet, catheter assembly, one-way valve and pull handle are comprised of radio-opaque material (0035).

14. Regarding claims 15 & 33, Breznock discloses a tube that includes a kink-resistant tube lumen wall (0010).

15. Regarding claims 16 & 18, and 34 & 35, 36, Breznock shows the kink-resistant lumen wall includes a first coiled monofilament polymer fiber (0003) and a second coiled monofilament fiber interwoven (0030).

16. Regarding claims 19 & 20, 34 & 37, Breznock shows the kink-resistant lumen wall including a first coiled monofilament metallic fiber (0030) interwoven with a second coiled monofilament metallic fiber (0030).

17. Regarding claim 38, Breznock shows the metallic fiber includes stainless steel (0030).

18. Claims 21 and 22 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea. Regarding claim 21, Breznock discloses a tube engaging a stylet, the tube having lumen with proximal and distal ports (fig 3B), a hub with proximal and distal face, the hub being attached to the tube, the lumen configured to form a passage for fluid continuous with tube lumen and dimensioned to

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receive a portion of stopper on stylet, in sealing engagement with tube lumen (3B), a one way valve in engagement with the hub distal face, the one-way valve configured so that the lumen is continuous with the passage hub lumen and tube lumen (3B). Shea (4,813,941) teaches an adhesive tab configured to draw and hold the hub in sealing engagement with the skin (column 4 lines 4-6). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity.

19. Regarding claim 22, Breznock also discloses a trocar obturator unit including the stylet with a point for puncturing the body, and a stopper coupled to stylet configured to position the stylet relative to catheter assembly (3B).

20. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea as applied to claims 1-4, 9-16, 18-24 and 28-38 above, and further in view of Ryan et al (5,693,031). Breznock in view of Shea disclose applicant's basic inventive concept of apparatus for treating pneumothorax and/or hemothorax substantially as claimed with the exception of the exterior of stopper or interior of one-way valve coated with a lubricant. Ryan et al shows this feature to be old in the medical devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Ryan et al to modify the apparatus of Breznock in view of Shea by adding lubricant (column 7 lines 55-60) to the exterior of stopper or interior of one-way valve so that the trocar is easily inserted into or removed from the catheter.

21. Claims 6-8 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea as applied to claims 1-4, 9-16, 18-24 and 28-38 above, and further in view of Calinog (3,703,899). Breznock in view of Shea disclose applicant's basic inventive concept of apparatus for treating pneumothorax and/or hemothorax substantially as claimed with the exception of the device comprising a pull-handle attached to the stopper, wherein said pull handle is a ring or is a tab. Calinog shows this feature to be old in the medical devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Calinog to modify the apparatus of Breznock in view of Shea by adding a pull handle (fig 5) of Calinog to the stopper in order to provide handle for the user operate the device more effectively.

22. In regards to claims 6, 7, 8, 25, 26, and 27, Shea's pull handle (fig 5 #11) can be a ring (fig 5) or a tab (fig 5), wherein said ring may be construed as a tab.

### ***Conclusion***

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,153,058 by Nehme discloses a Pleural Decompression Catheter. WO 95/18642 by Omirana discloses and Adhesive Surgical Retaining Device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8am - 4:30pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle  
Examiner  
Art Unit 3763

MAM  
8/19/05

  
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